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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/770,901	01/26/2001	Joaquina Faour	PHUS-28	7749

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EXAMINER

JIANG, SHAOJIA A

ART UNIT PAPER NUMBER

1617

DATE MAILED: 03/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/770,901

Applicant(s)

FAOUR ET AL

Examiner

Shaojia A. Jiang

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2005 and 01 October 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-15, 18-37 and 49-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-15, 18-37 and 49-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/1/04.
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a response to Applicant's amendment and response filed on January 6, 2005 and October 1, 2004 wherein claims 1-10, 16-17, and 38-48 are cancelled; claims 11-15, 18-37, and 49-56 have been amended.

Currently, claims 11-15, 18-37, and 49-56 are pending in this application.

Claims 11-15, 18-37, and 49-56 as amended now are examined on the merits herein.

Applicant's amendment filed January 6, 2005 with respect to the rejection of claims 1, 4-6, 10-15, 18-38, 43-45, 48 and 55, made under 35 U.S.C. 112, first paragraph, for lack of full scope of enablement for all COX-II inhibitors in combination with all muscle relaxants recited in the claims herein of record in the previous Office Action dated July 1, 2004 have been fully considered and found persuasive to remove the rejection since claims 1-10 are cancelled, and the rest of claims have been amended to dependent from claim 49. Therefore, the said rejection is withdrawn.

Applicant's amendment and remarks filed January 6, 2005 with respect to the rejection of claims 6, 33, 50, and 53-54 made under 35 U.S.C. 112 second paragraph for the use of the indefinite recitations of record stated in the Office Action dated July 1, 2004 have been fully considered and found persuasive to remove the rejection since claim 6 is cancelled and claims 33, 50, and 53-54 have been amended. Moreover, "an acidifying agent, adsorbent, alkalizing agent, antioxidant, buffering agent, ...solvent, oil,

soap, detergent" recited in claim 50 are seen to be defined and supported in the specification at page 23-29. Therefore, the said rejection is withdrawn.

Applicant's amendment filed January 6, 2005 with respect to the rejection of claim 1, 4-6, 10-15, 18-38, 43-45, 48 and 55 made under 35 U.S.C. 103(a) as being unpatentable over Gans et al. or Futaki et al. (of record) in view of Okada et al. (5,476,663, of record) have been considered and found persuasive to remove this particular rejection of record stated in the Office Action dated July 1, 2004, since claims 1-10 are cancelled, and the rest of claims have been amended to dependent from claim 49. Therefore, the said rejection is withdrawn.

Note that the rejection of claims 49, 51, and 52 under 35 U.S.C. 103(a) over the same references has been overcome of record in the previous Office Action, because of the unexpected results of the particular combination of claim 49.

The following is the new ground(s) of rejection(s).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11-15, 18-37, and 49-56 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14-15 of U.S. Patent No. 6,753,011.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent is drawn to a device for the controlled delivery comprising the first and second agents, wherein the first agent is pridinol and the second agent is a selective or specific COX-II inhibitor agent. According the specification of the patent, COX-II inhibitors include rofecoxib and celecoxib (see col.16 line 35-36). It is proper to use the specification to interpret what the applicant meant by a word or phrase recited in the claim.

The claims of the instant application are a pharmaceutical composition comprising a COX-II inhibitor selected from the group of rofecoxib and celecoxib and pridinol. Moreover, the pharmaceutical composition in the instant claims is also directed to a controlled release form.

Thus, the device in claims 14-15 of the patent is deemed to comprise the same pharmaceutical composition as instantly claimed.

Therefore, the instant claims are seen to be obvious over the claims 14-15 of U.S. Patent No. 6,753,011.


In view of the rejections to the pending claims set forth above, no claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703.872.9307.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



S. Anna Jiang, Ph.D.
Primary Examiner
Art Unit 1617
March 18, 2005